LISTEN. THINK. SOLVE.®

# Rockwell Automation

## Introduction


## Deon Engelbrecht
## Information Solutions Executive


PUBLIC

Allen-Bradley • Rockwell Software

Rockwell Automation



Copyright © 2014 Rockwell Automation, Inc. All Rights Reserved.

# Mass Serialisation through the “Internet of Things” (IoT

Rockwell Automation

PUBLIC

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved. 

# Mass Serialisation through the “Internet of Things” (IoT

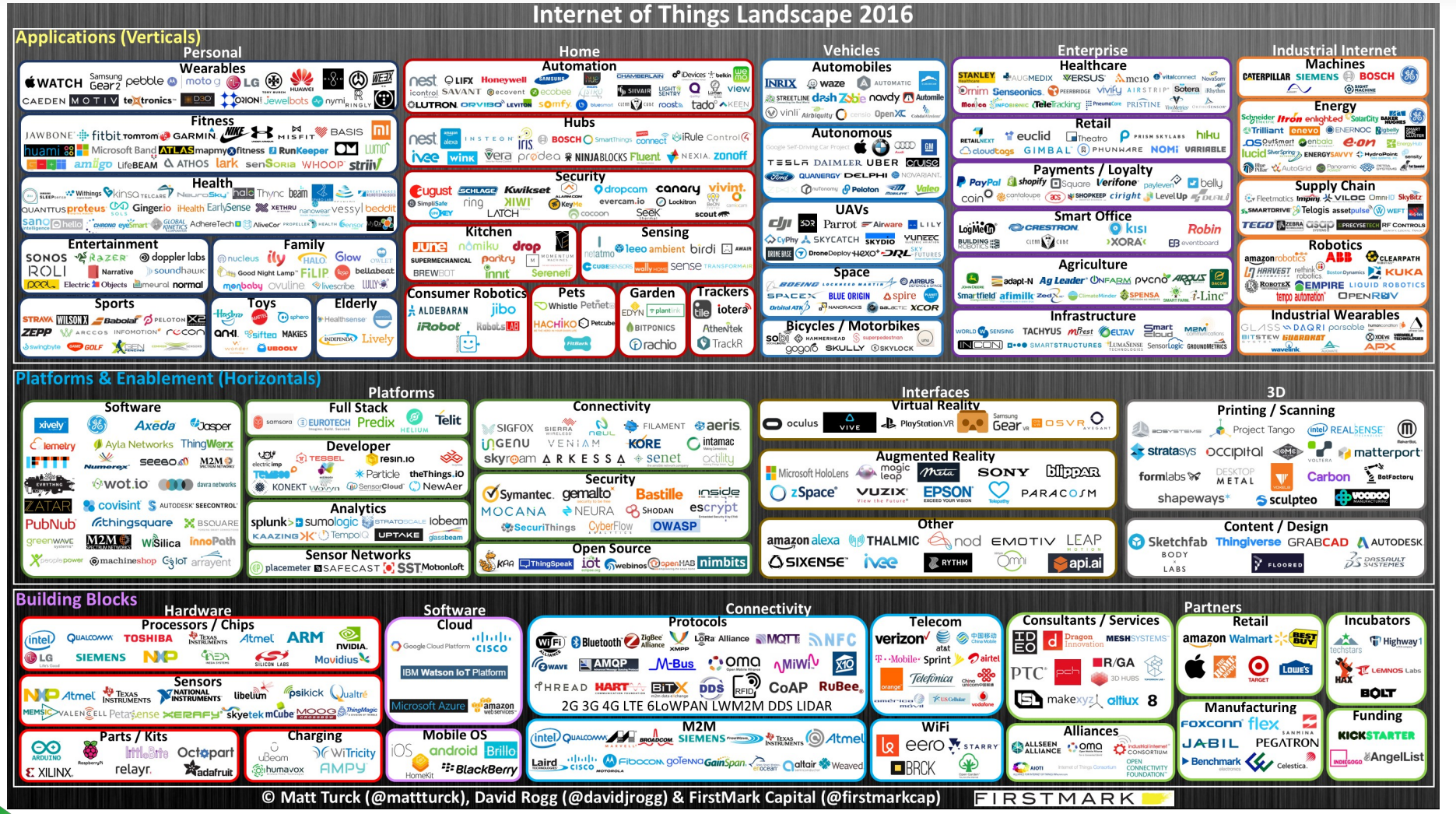
Rockwell Automation

PUBLIC

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved. 

# IOT (Internet of Things)

Rockwell Automation

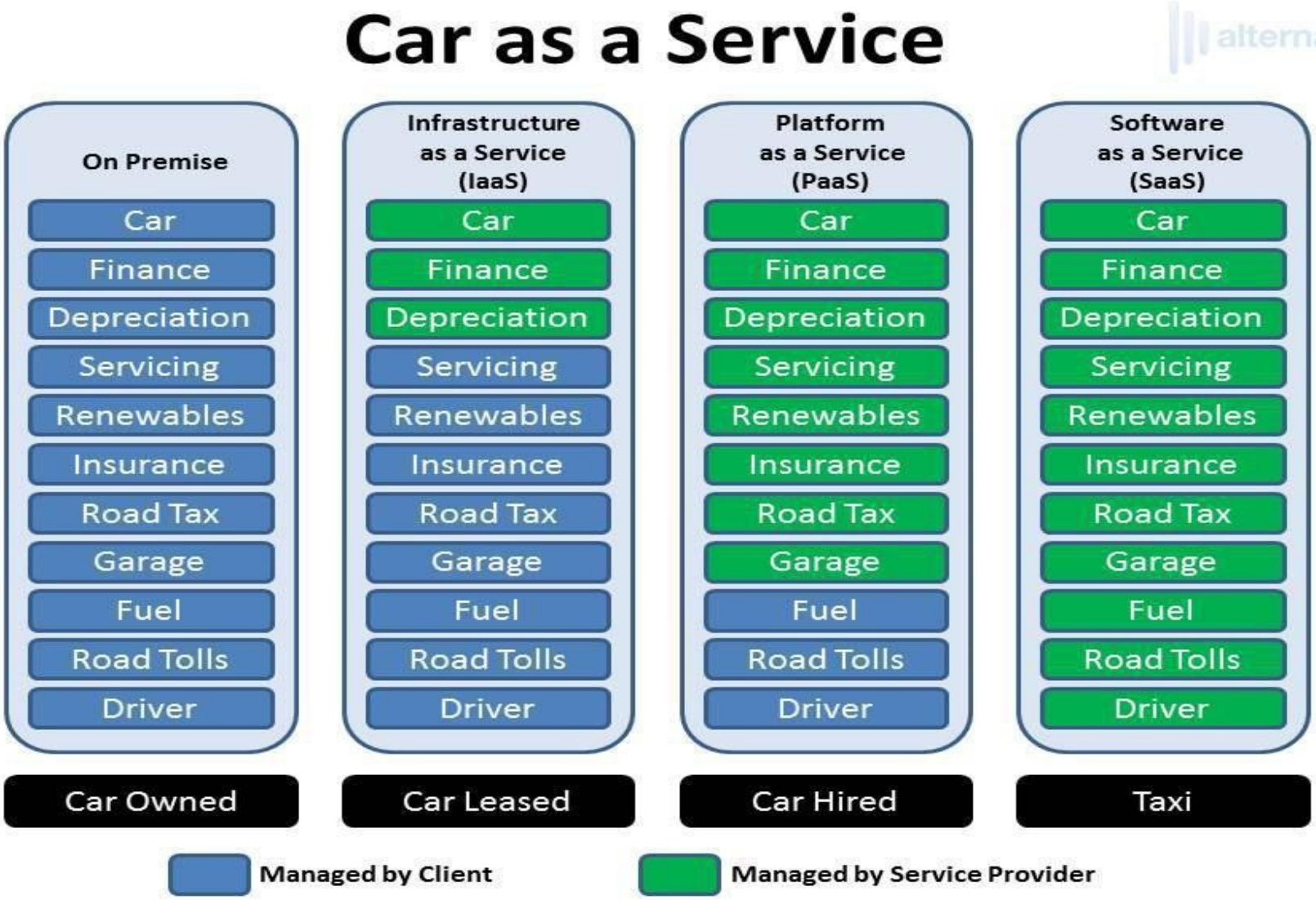




Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

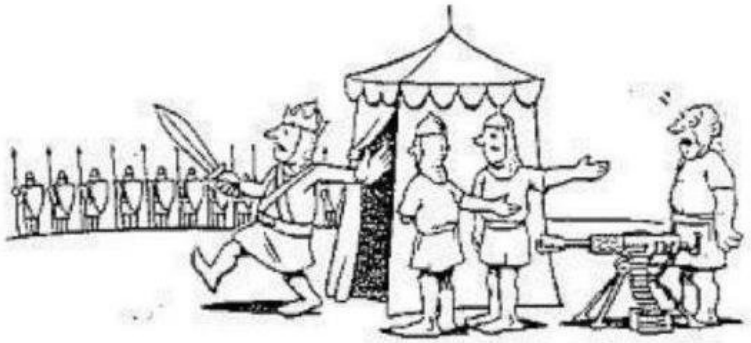
# SaaS (Software as a Service)

Rockwell Automation

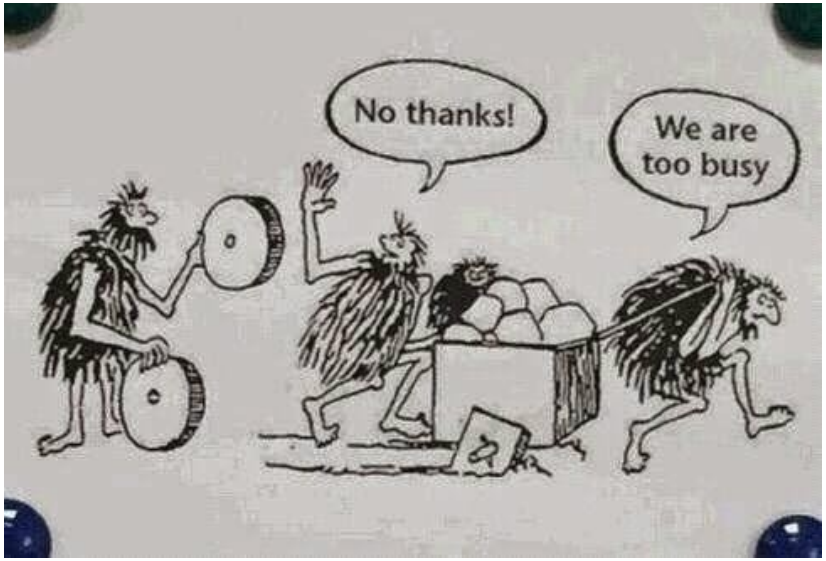




Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.



"I don't have time to see any crazy salesman; I have a battle to fight."





Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

LISTEN. THINK. SOLVE.®

# Serialization Solutions

**Deon Engelbrecht**

**Information Solutions Executive**

PUBLIC

Allen-Bradley • Rockwell Software

Rockwell Automation



Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Agenda

Rockwell Automation

**Market Trends**

Regulations & Requirements

Implementation Challenges

PUBLIC

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved. 

# Why Serialize?

Rockwell Automation

| Business Category | Business Benefit |
|---|---|
| **CONSUMER SAFETY/ BRAND PROTECTION** | • Regulatory compliance<br>• Product adulteration control<br>• Diversion source & location control |
| **CUSTOMER SERVICE & RETURNS PROCESSING** | • Authenticate transactions<br>• Improve chargeback payment accuracy |
| **SUPPLY CHAIN INTEGRITY** | • Complete Supply Chain Traceability<br>• Increase recall accuracy & efficiency<br>• Direct to customer notifications |
| **SUPPLY CHAIN OPTIMIZATION** | • Improve forecasting<br>• Optimize inventory<br>• Improve supply chain planning |
| **Marketing & BRAND LOYALTY PROGRAMS** | • Real-time consumer & product market data<br>• Customer-specific target marketing programs<br>• Consumer authentication via mobile device |
| **BUSINESS OPTIMIZATION – Connected Enterprise** | • Share data across departments: Sales, Marketing, Finance, Operations, Supply Chain, etc. |

PUBLIC

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Market Trends:
## Global Medicinal & Food Product Safety

Rockwell Automation

The World Health Organization estimates counterfeit drug sales to range between $35 and 40 billion per year. Between 8 and 10% of the worldwide drug supply is estimated to be counterfeit.

- Growing health and safety risk with counterfeited drugs
- Growing involvement in the drug supply chain of under-regulated wholesalers and re-packagers
- Proliferation of Internet pharmacies, advancements in technology that make it easier to produce counterfeit drugs
- Increased importation of gray market medicines
- Ex: the 2008 contamination of Chinese infant formula

PUBLIC
Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Agenda

Rockwell Automation

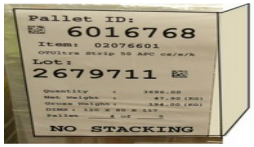
Market Trends

**Regulations & Requirements**

PUBLIC

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved. 

# Serialization Requirements

| Blister Pack (Unit) | Bundle | Case | Pallet |
|---|---|---|---|
| | | | |
| | | |   |
| 8305254961 | 4693602591<br>8305254961 | 1112131415<br>4693602591<br>8305254961 | 1452267440<br>1112131415<br>4693602591<br>8305254961 |

**Human readable unique serial number**

- On each package (USA)
- On primary package (EU)

**Aggregation** of all primary package serial numbers to their lower level sub-package serial numbers in parent/child relationships


Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Data Example: Pharma market in the EU

- The EFPIA directive for coding of pharmaceutical products in Europe include:
  - GTIN product code
  - Serial number (Unique Identifier)
  - Batch or lot number
  - Expiry date
  - Data Matrix 2D Code

GTIN 00314141999995
SN 10000000234
LOT 987654321GFEDCBA
EXP 01/2015

PUBLIC
Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Serialization Requirements

Rockwell Automation

### *Track & Trace*
Track & trace raw materials

### *Scan*
Codes to verify authenticity of product

### *Generate*
Acquire, Manage UID for each saleable item

### *Validate*
Serialization data matches the physical product received

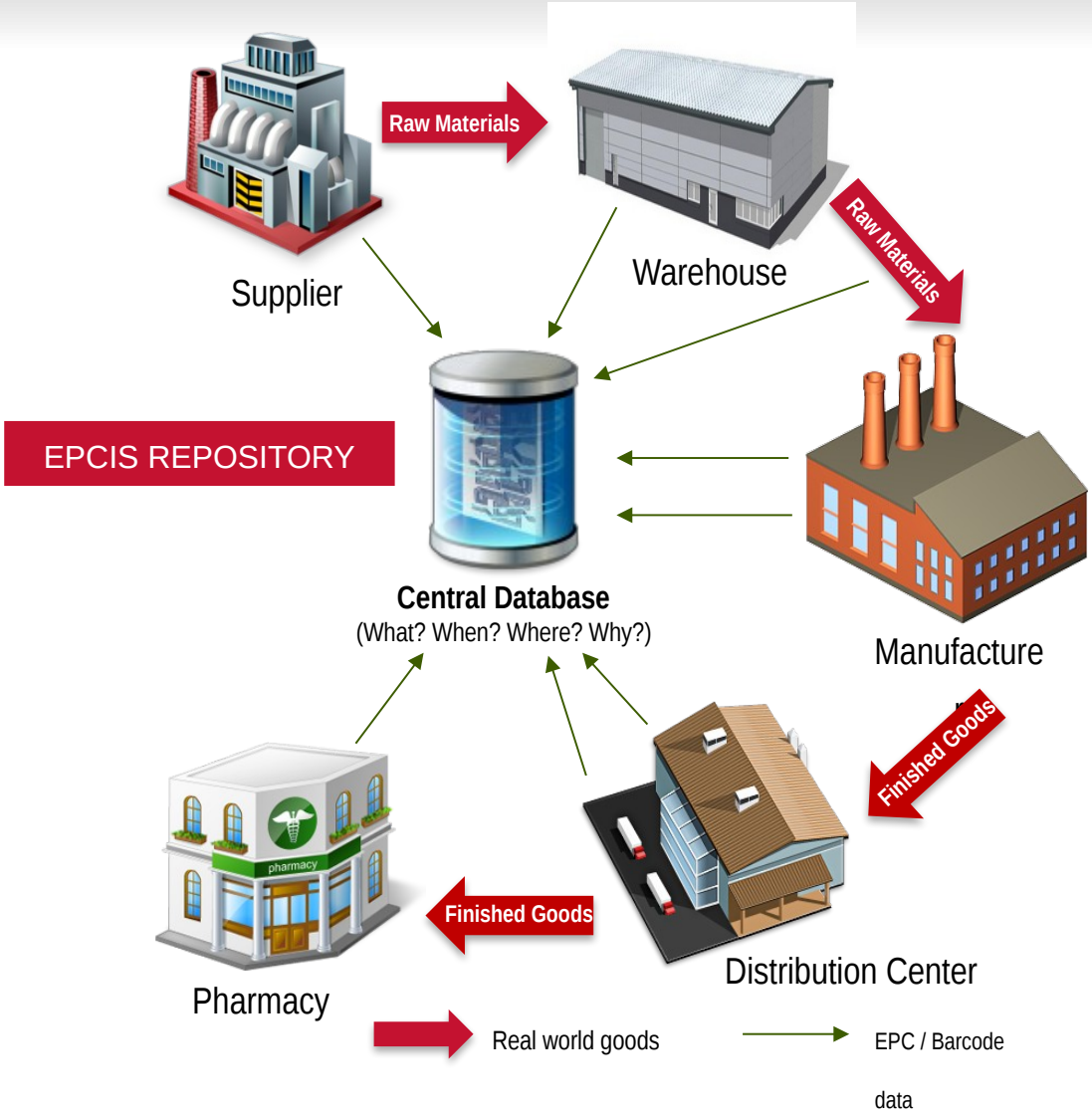
### *Aggregate*
Serial numbers in Parent/Child Data relationships

### *Track*
Status of dispensed items to prevent re-use of serial numbers

### *Store*
Code information in a secure database

### *Confirm*
That products have complete and accurate documentation

### *Associate*
Code information when dispatching products




PUBLIC
Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# Regulations

***Regulations and industry standards specify what but not how to implement Serialization.***

| EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | FDA | CFDA |
|---|---|---|
| **EU Falsified Medicines Directive** | **Drug Supply Chain Security Act (U.S.)** | **China Food & Drug Administration** |
| Directive 2001/83/EC- prevention of the entry of falsified medicinal products | Identification of suspect product and notification | Electronic Drug Supervision Code (EDSC) |

- *Other countries, including Brazil, have begun instituting increased government regulations.*
- In Australia, **GS1 Australia** is the only organisation authorised to register and issue barcode numbers

PUBLIC
Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

# GS1, EPCIS & Global Interoperability

Rockwell Automation

## ALL COUNTRIES WITH THE EXCEPTION OF CHINA ARE FOLLOWING THE GS1 STANDARDS

*GSI - An International not for-profit association with over 100 country organizations*

- Design and implement global standards and solutions that improve efficiency and visibility of supply and demand chains globally across sectors.
- Most widely used supply chain standards system in the world.

*GS1 Standards*

- Barcode Standards
- Data Accuracy Standards
- eCom Standards
- Electronic Product Code (EPC) Standards
- Global Data Synchronization Network (GDSN) Standards
- Global Data Dictionary
- Global Product Classification (GPC) Standards
- Extensible Markup Language (XML) Standards

*EPCIS: Electronic Product Code Information Services*

- Enables disparate applications to leverage EPC data via EPC-related data sharing, both within and across enterprises

Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.

LISTEN. THINK. SOLVE.®

# Thank You

PUBLIC

Allen-Bradley • Rockwell Software

Rockwell Automation



Copyright © 2015 Rockwell Automation, Inc. All Rights Reserved.